

FEB - 1 2001

K003615
Special 510(k)
SteriChek Sensitive Feed Water and Rinse Water Reagent Strips
Environmental Test Systems, Inc.

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: November 21, 2000

Submitter: Environmental Test Systems, Inc.

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Elkhart, IN 46514
U.S.A.
(219) 262-2060

Contact: David A. Morris, Ph.D.
Vice President, Technology

Device Trade/
Proprietary Name: **SteriChek™ Sensitive - Feed Water and Rinse Water Reagent Strips**

Device Common Name: Total Chlorine Reagent Strips

Classification Name: Class II
CH

Predicate Device: **SteriChek™ Total Chlorine Reagent Strips**

Device Description: The device is made up of a 0.20 inch square yellow reagent pad that has been chemically treated and affixed to one end of a 3.25 inch by 0.20 inch white opaque polystyrene strip. The reagent pad is activated by exposing it to the sample. The color of the pad is visually compared to a color chart to determine the amount of total chlorine present in the sample.

Intended Use: SteriChek™ Sensitive - Feed Water and Rinse Water Reagent Strips provide a convenient means for measuring the concentration of chlorine bleach remaining in water being used to rinse out dialysate lines following disinfection of hemodialysis equipment, and for testing for low levels of total chlorine (i.e. total chloramines plus free chlorine) in feed water used to prepare dialysate.

Technological
Characteristics:

The concentration of chlorine in rinse water is obtained by comparing the color of the reagent pad with color blocks on the label. The color blocks are calibrated in terms of chlorine concentration in parts per million (ppm). The device is used as a quantitative method to detect total chlorine concentrations between 0 and 3 ppm. The device will reliably measure total chlorine concentrations as low as 0.1 ppm total chlorine.

SteriChek™ Sensitive - Feed Water and Rinse Water Reagent Strips contains two indicators, an activating surfactant, and other non-reactive ingredients. Free chlorine and combined chlorine (chloramines) react with the indicators to form colored complexes. The amount of the colored complexes is dependent on the concentration of free chlorine and combined chlorine in the sample.

Assessment of
Performance:

The performance characteristics of SteriChek™ Sensitive Feed Water and Rinse Water Reagent Strips and the predicate device were analyzed with water samples in which either sodium hypochlorite or chloramines were added to give a range of free chlorine or combined chlorine levels. The performance was equivalent.

Conclusion:

The SteriChek™ Sensitive - Feed Water and Rinse Water Reagent Strips have the same intended use as the predicate device. Both systems effectively measure the total free and combined chlorine levels in water. The SteriChek™ Sensitive - Feed Water and Rinse Water Reagent Strips have no technological characteristics that raise new types of safety or effectiveness questions.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850David A. Morris, Ph.D.
Vice President, Technology
Environmental Test Systems, Inc.
P.O. Box 4659
ELKHART IN 46514Re: K003615
SteriChek™ Sensitive Feed Water and
Rinse Water Reagent Strips
Dated: December 27, 2000
Received: January 2, 2001
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FKP, LIF

Dear Dr. Morris:

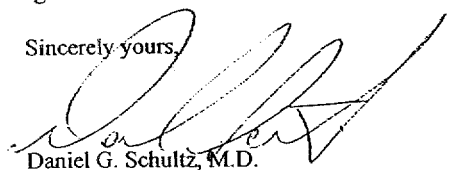
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known) K003615

Device Name: SteriChek™ Sensitive - Feed Water and Rinse Water Reagent Strips

Indications for Use:

SteriChek™ Sensitive - Feed Water and Rinse Water Reagent Strips provide a convenient means for measuring the concentration of chlorine bleach remaining in water being used to rinse out dialysate lines following disinfection of hemodialysis equipment, and for testing for low levels of total chlorine (i.e. total chloramines plus free chlorine) in feed water used to prepare dialysate.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

David A. Rogers
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K003615